510(k) Summary
Nexus Anterior Cervical Plate System
Premarket Notification

JUL 1 1 2013

SUBMITTED BY	Core-Nexus 15760 Ventura Blvd 7th Floor Encino, CA 91436
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Thomas Palmer President Core-Nexus Email: tpalmer@core-nexus.com Phone: 818-424-4270
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Email: lpeterson@kaedonconsulting.com Phone: 512-507-0746
DATE PREPARED	May 15, 2013
CLASSIFICATION NAME	Spinal Intervertebral Body Fixation Orthosis
DEVICE CLASS	Class II
REGULATION NUMBER	888.3060 (Product Code KWQ)
COMMON NAME	Anterior Cervical Plate System
PROPRIETARY NAME	Nexus Anterior Cervical Plate System
IDENTIFICATION OF PREDICATE DEVICE(S)	Dio Medical Rex Anterior Cervical Plate System (K121862)

DEVICE DESCRIPTION

The Nexus Anterior Cervical Plate System consists of a variety of shapes and sizes of main plates, screws, sub-plates, rivets and associated instruments. The sub-plate is pre-assembled to the main plate and designed to prevent screws from backing out using the elastic behavior during the screw insertion.

The rivets are pre-assembled to the main plate, which firmly attach the sub-plate component to the main plate. Each component is color anodized to differentiate the screw type and diameter and to facilitate the surgical process.

The plates range in length to accommodate one, two, three, and four level procedures. Main plates are available from 20mm to 110mm. Screws are available in lengths from 10mm to 20mm in 2mm increments. The screws have either a 3.5mm or 4.0mm diameter. They are provided in fixed self-tapping, variable self-tapping, fixed self-drilling and variable self-drilling configurations.

INDICATIONS

The Nexus Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this Special 510(k) is to obtain clearance to market the subject device as the Nexus Anterior Cervical Plate System. The subject device was previously cleared as the Dio Medical Rex Anterior Cervical Plate System (K121862). Documentation demonstrating the legal right to distribute the Nexus Anterior Cervical Plate System is maintained at Core-Nexus.

The subject device is identical to the previously cleared Rex System in terms of indications for use, device dimensions, instrumentation, manufacturing process, cleaning/sterilization process and labeling. The System implant components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

DISCUSSION OF NON-CLINICAL TESTING

Non-clinical testing was not performed as part of this submission.

CONCLUSIONS

The subject device is identical to the predicate device in terms of indications for use, device dimensions, instrumentation, manufacturing process, cleaning/sterilization process and labeling. Documentation was provided as part of this Special 510(k) to demonstrate that the Nexus Anterior Cervical Plate System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2013

Core-Nexus
% Mr. Thomas Palmer
President
15760 Ventura Boulevard, 7th Floor
Encino, California 91436

Re: K131520
Trade/Device Name: Nexus Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 10, 2013
Received: June 13, 2013

Dear Mr. Palmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131520

Device Name: **Nexus Anterior Cervical Plate System**

Indications for Use:

The Nexus Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices